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10/824,919	04/14/2004	James J. Modliszewski	60306-USA	7365

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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,919	MODLISZEWSKI ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-38* is/are pending in the application.

4a) Of the above claim(s) *23-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 5-22 and 29-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 3/6/08 are acknowledged.

2. Claims 3-4 were cancelled. Claims 23-28 were withdrawn from consideration.

3. Claims 1, 7 and 17 were amended.

4. Claims 1-2, 5-22 and 29-38 are included in the prosecution.

Response to Arguments

Rejection of claim 17 under 35 USC § 112, second paragraph

5. In light of Applicant's amendment of claim 17, the rejection under 35 USC § 112, second paragraph is withdrawn.

Rejection of claims 1-22, 29-34 and 36-38 under 35 USC § 103(a)

6. Applicant's arguments, see Page 7, filed 3/6/08, with respect to the rejection of claims 1-22, 29-34 and 36-38 under 35 USC § 103(a) as being unpatentable over Gilleland et al. (US 6,375,981) in view of Colegrove (US 6,509,311) have been fully considered but are not found persuasive.

Applicant argues that the Examiner has not explained where in Colegrove et al. one skilled in the art would find suggestion that the propylene glycol alginate used in the gels disclosed therein for personal care formulations could also be used in the homogeneous, thermoreversible gel films of the present invention that are useful, for example, in the preparation of soft capsules. Applicants submit that persons skilled in the art would not be motivated to use the propylene glycol alginate disclosed in Cade et al. in the soft gel films and capsules of Gilleland et al.

This is not found persuasive because Colegrove teaches that historically, propylene glycol alginates "have not been considered for gel formation, or for the production of useful gels" (Col. 1, lines 25-26). However, Colegrove also teaches "a gel system comprising propylene glycol alginate and an aluminum salt" (Col. 1, lines 29-30). Colegrove teaches: "Gel textures ranging from soft and elastic to firm and rigid can be made herein as the components are varied. For example, propylene glycol alginates with a high degree of esterification generally will produce soft, elastic gels while a lower degree of esterification will provide firm, brittle gels" (Col. 1, lines 62-67). Therefore, one with ordinary skill in the art would know from the teaching of Colegrove that it is possible to prepare various gel textures from propylene glycol alginates. Since capsule shells are known in the art to be made of soft, elastic gels or hard gels, it is not surprising, i.e. it would be obvious to one of ordinary skill in the art to use the propylene glycol alginate taught by Colegrove in a formulation that requires gel or film formation. One with ordinary skill in the art would be motivated to make capsule formulations where the capsule wall is prepared with a gel or film forming composition (as taught by Gilleland - Col. 2, lines 25-33) and try the propylene glycol alginate gel (as taught by Colegrove) as the capsule wall material with a reasonable expectation of success.

Therefore, the rejection of 9/6/07 is maintained.

Rejection of claim 35 under 35 USC § 103(a)

7. Applicant's arguments, see Page 8, filed 3/6/08, with respect to the rejection of claim 35 under 35 USC § 103(a) as being unpatentable over Gilleland et al. (US 6,375,981) in view of Cade (US 6,517,865) have been fully considered.

Applicant argues that in amended claim 1, the alginate is at least one of propylene glycol alginate or salts or said alginate and combinations thereof. Applicant argues that Cade does not disclose the use of propylene glycol alginate. In light of Applicant's amendment of instant claim 1 to include the limitation of propylene glycol alginate, the rejection of 9/6/07 is withdrawn. However, new grounds of rejection, necessitated by Applicant's amendment, follow.

Provisional Rejection of claims 1, 2, 8-11, 17, 22, and 35 under nonstatutory obviousness-type double patenting

8. Applicant failed to respond to the provisional rejection of claims 1, 2, 8-11, 17, 22, and 35 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10-15, 23-25 of copending Application No. 10/824,957. Applicant did not point out that the obviousness-type double patenting rejection was improper. This is considered non-responsive. Applicant must point out the reasons why the obviousness-type double patenting rejection is improper or file a terminal disclaimer in order to be responsive. Until such time that a terminal disclaimer is filed, the obviousness-type double patenting rejection of 9/6/07 will be maintained.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-2, 5-22, 29-34, and 36-38 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gilleland et al. (US 6,375,981) in view of Colegrove (US 6,509,311).

The claimed invention is a homogenous, thermoreversible gel film comprising a film-forming amount of a water soluble, thermoreversible alginate and optionally at least one of a plasticizer, a second film former, bulking agent, and a pH controlling agent.

Gilleland teaches soft gel film forming compositions comprising starch, gum, and plasticizer and can be used as a gelatin replacement (Col. 1, lines 51-59). A "soft gel capsule that comprises a sealed capsule wall and a first substance that is encapsulated by the capsule wall" is disclosed (Col. 2, lines 25-29). The film or capsule wall consists essentially of the combination of starch material, gum, and plasticizer (Col. 2, lines 30-33). The film-forming composition preferably comprises "25-75% starch material, 25-75% plasticizer, and 0.1-15% gum" (Col. 1, lines 62-68). The starch material is disclosed as chemically modified starch such as derivatives (ether and ester) of starch (Col. 2, lines 1-9). The gum is selected from alginates, carrageenan, locust bean, xanthan, gellan, agar, guar, gum arabic and pectin (Col. 2, lines 13-15). The plasticizer comprises at least one polyol such as glycerol, sorbitol, and maltitol (Col. 2, lines 17-20). Monovalent or divalent cations such as calcium are disclosed as optional ingredients for the composition (Col. 2, lines 20-23). Substances that can be encapsulated by the capsule wall include drugs, vitamins, and nutritional supplements (Col. 2, lines 36-38). Additives such as flavorings agents are also disclosed (Col. 4, lines 51-54). Thermo-reversibility of the films was assessed (Col. 6, lines 15-18 and

Table 1) along with tensile strength measurements (Col. 6, lines 33-34). It is disclosed that "edible films are prepared by blending together the starch, gum, plasticizer, and water, and heating the mixture to a temperature and for a time sufficient to gelatinize the starch fully ..." (Col. 3, lines 3-6). Also, suitable additives that may be incorporated into the composition without any adverse effects on the properties exhibited by the composition include flavoring agents (Col. 4, lines 49-56).

Gilleland does not expressly teach propylene glycol alginates.

Colegrove teaches propylene glycol alginate gels (Col. 1, lines 20-26). Colegrove teaches that historically, propylene glycol alginates "have not been considered for gel formation, or for the production of useful gels" (Col. 1, lines 25-26). However, Colegrove also teaches "a gel system comprising propylene glycol alginate and an aluminum salt" (Col. 1, lines 29-30). Colegrove teaches: "Gel textures ranging from soft and elastic to firm and rigid can be made herein as the components are varied. For example, propylene glycol alginates with a high degree of esterification generally will produce soft, elastic gels while a lower degree of esterification will provide firm, brittle gels" (Col. 1, lines 62-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the composition comprising alginate as the gum, starch, and plasticizer for soft gel films and gelatin replacement capsules and assess the thermo-reversibility of the films, as suggested by Gilleland, use the propylene glycol alginates as the gel film forming material, as suggested by Colegrove, and produce the instant invention.

Therefore, one with ordinary skill in the art would know from the teaching of Colegrove that it is possible to prepare various gel textures from propylene glycol alginates. Since capsule shells are known in the art to be made of soft, elastic gels or hard gels, it is not surprising, i.e. it would be obvious to one of ordinary skill in the art to use the propylene glycol alginate taught by Colegrove in a formulation that requires gel or film formation. One with ordinary skill in the art would be motivated to make capsule formulations where the capsule wall is prepared with a gel or film forming composition (as taught by Gilleland - Col. 2, lines 25-33) and try the propylene glycol alginate gel (as taught by Colegrove) as the capsule wall material with a reasonable expectation of success.

Regarding instant claim 1, the limitation of the homogenous thermoreversible gel film would have been obvious to one skilled in the art over the film forming composition taught by Gilleland because the film forming composition taught by Gilleland can be used to form capsules. One skilled in the art would know that the film-forming and encapsulating material would have to be uniform or homogenous to avoid films and capsules that have lumps of unmixed components which leads to brittleness and instability. The thermoreversible alginate would have been obvious to one skilled in the art over the thermoreversible film formulation taught by Gilleland. The film-forming amount of the alginate would have been obvious over the percentage of gum in the film-forming composition taught by Gilleland. The plasticizer would have been obvious over the plasticizers glycerol, sorbitol, and maltitol taught by Gilleland. The second film former and bulking agent would have been obvious over the starch taught by Gilleland.

The pH controlling agent would be a component that one skilled in the art would use in the composition in order to optimize the gel film strength and stability during the process of routine experimentation.

Regarding instant claims 2 and 5, the limitation of the second film former would have been obvious to one skilled in the art over the starch derivatives, carrageenan, gums, and pectin taught by Gilleland.

Regarding instant claim 6, the limitation of the amount of alginate being at least 10% of the film formers would have been obvious to one skilled in the art over the 0.1-15% gum in the gel film formulation taught by Gilleland.

Regarding instant claim 7, the limitation of the alginate would have been obvious to one skilled in the art over the alginates taught by Gilleland and the propylene glycol alginate taught by Colegrove. The starch derivatives, sorbitol, and glycerin would have been obvious over the starch derivatives, sorbitol, and glycerol taught by Gilleland.

Regarding instant claims 8-11, the limitation of the break force of the film would have been obvious to one skilled in the art over the alginate based gel film and tensile strength measurement taught by Gilleland because one skilled in the art would use texture analyzers to test the strength of the gel films during routine optimization. The recited break force figures are obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 12-16, the limitation of solids content of the gel film would have been obvious to one skilled in the art over the teaching by Gilleland that the

solids concentration in the composition will be about 30-70% by weight (Col. 1, lines 60-61). One with ordinary skill in the art would vary the solids content in the gel film composition during the process of routine experimentation in order to optimize the film stability and capsule formation. The limitations of solids content greater than 70% (instant claims 15 and 16) are obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claim 17, the limitation of the plasticizer would have been obvious to one skilled in the art over the plasticizers glycerol, sorbitol, and maltitol taught by Gilleland. The second film former and bulking agent would have been obvious over the starch and starch derivatives taught by Gilleland. The polyvalent cation limitation would have been obvious over the cations (such as calcium) disclosed by Gilleland.

Regarding instant claim 18, the limitation of alginate being the only film former in the gel film would have been obvious to one skilled in the art over the propylene glycol alginate gels taught by Colegrove (Col. 2, examples 1-6, lines 25-67).

Regarding instant claim 19, the limitation of the second film former would have been obvious to one skilled in the art over the carrageenan taught by Gilleland.

Regarding instant claims 20, 34, and 38, the limitation of soft capsules comprising the film would have been obvious to one skilled in the art over the soft gel capsule (produced from the film forming composition) comprising a sealed capsule wall and an encapsulated substance taught by Gilleland.

Regarding instant claim 21, the limitation of the capsule shell having a solids content of at least 50% would have been obvious over the soft gel capsules taught by Gilleland because one skilled in the art would modify the solids content of the film forming composition in order to optimize capsule shell formation, capsule sealing, and capsule stability.

Regarding instant claim 22, 34, and 38, the limitation of the encapsulated substance would have been obvious to one skilled in the art over the drugs, vitamins, and nutritional supplements that can be encapsulated by the capsule wall, as taught by Gilleland.

Regarding instant claims 29-31, the limitations of a solid form encapsulated by the gel film, a fill material, and a hard capsule, would have been obvious to one skilled in the art over the capsule wall (produced from the film forming composition) that encapsulates "any variety of materials which have been encapsulated by gelatin in the past", as taught by Gilleland (Col. 2, lines 34-36). One skilled in the art would know that the recited fill materials (powder, tablet, caplet, microcapsule or capsule) are readily encapsulated by gelatin capsules (hard capsules and soft capsules) and can be encapsulated by the capsule (produced from the film forming composition) as taught by Gilleland.

Regarding instant claims 32-33, the limitation of having a polyvalent cation level of 5% or less and 2% or less would have been obvious to one skilled in the art over the optional inclusion of cations in the film forming composition taught by Gilleland. One

skilled in the art would minimize the amount of cations, as they are known in the art to cross link with alginates.

Regarding instant claims 36-37, the limitation of the gel film containing the alginate, flavorant and water would have been obvious to one skilled in the art over the Gilleland teaching that edible films are prepared by blending the starch, gum, plasticizer, and water. The limitation of flavorant as corn syrup would have been obvious over the Gilleland teaching that additives such as flavoring agents can be used in the composition. One skilled in the art would know that corn syrup is a readily available flavoring agent and would use it as an additive in the composition.

11. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilleland et al. (US 6,375,981) in view of in view of Colegrove (US 6,509,311) and further in view of Cade et al. (US 6,517,865).

The teachings of Gilleland and Colegrove are stated above.

Gilleland and Colegrove do not expressly teach a composition without a plasticizer.

Cade teaches polymer film compositions for hard and soft capsules comprising water-soluble cellulose ethers, hydrocolloids and sequestering agents (Abstract). Cellulose ethers such as alkyl celluloses are disclosed (Col. 1, line 66 to Col. 2, line 4). Hydrocolloids such as gellan, alginates, carrageenan, pectin, starch, pullalan, and dextran are disclosed along with the amount of gum being between 0.01 to 2% (Col. 2, lines 10-29). Sequestering can be adjusted by the addition of monovalent or divalent

cations such as Ca^{++} or Mg^{++} (Col. 2, lines 38-40). The plasticizers disclosed include polyethylene glycol, glycerol, and sorbitol, with amounts ranging from 0 to 40% (Col. 2, lines 55-62). The examples include compositions 1-4, which do not include plasticizer (Col. 3, lines 46-56).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the film forming thermoreversible composition comprising alginate as the gum, as suggested by Gilleland, use the propylene glycol alginates as the gel film forming material, as suggested by Colegrove, further combine it with the film composition without plasticizer, as suggested by Cade, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Cade teaches that plasticizer can be at 0% in the composition and capsules made with the composition "have a non-animal polymer composition, an improved dissolution behavior, an enhanced elasticity and show higher transparency" (Col. 2, lines 46-48).

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1, 2, 8-11, 17, 22, and 35 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10-15, 23-25 of copending Application No. 10/824,957 ('957 hereinafter).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a homogenous, thermoreversible gel film comprising a film-forming amount of a water-soluble, thermoreversible alginate and optionally at least one of a plasticizer, a second film former, bulking agent, and a pH controlling agent. Claims of '957 are also drawn to a delivery system comprising a homogenous, thermoreversible gel film that comprises a film-forming amount of a water soluble, thermoreversible alginate and optionally at least one of a plasticizer, a second film former, bulking agent, a pH controlling agent, and an active substance. The difference between the claims is that the claims of '957 include the limitation of an active substance. However, instant claims also include encapsulated substances selected from pharmaceuticals, vitamins, nutritional supplements etc. Therefore, it would have been obvious to one skilled in the art to include an active ingredient for encapsulation by the thermoreversible gel film. Since the instant

application claims encapsulated substances by thermoreversible gel films, it is obvious over the claims of '957 and thus they are not patentably distinct over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

14. No claims are allowed.

15. Since the new rejection was necessitated by applicant's amendment, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615